Section 5 - 510(k) summary

JUN - 8 2011

(as described in CFR 807.92 Content and format of a 510(k) summary chapter (a), (1) to (6))

(1)

Submitted by: ERKA. Kallmeyer Medizintechnik GmbH & Co. KG
Im Farchet 15
83646 Bad Tölz
Germany
Tel.: +49 (0)8041 / 8009-0
Fax: +49 (0)8041 / 8009-39

Contact: Jan Weiss, Quality Manager

Date prepared: 24 November 2010

(2)

Name of Device: ERKA. Perfect-Aneroid sphygmomanometer

Common Name: Blood Pressure Sphygmomanometer

Classification Name: Blood Pressure Cuff; DXQ; 870.1120

(3)

Predicate Device: RUDOLF RIESTER PRECISA N Blood Pressure Sphygmomanometer
510(k) Document Control No.: K972379

(4)

Description of the device:
The ERKA. Perfect-Aneroid Sphygmomanometer is an established manual non-invasive blood pressure measurement device that facilitates the auscultatory measuring method of Riva Rocci / Korotkoff. The ERKA. Perfect-Aneroid Sphygmomanometer is designed to non-invasively measure the systolic and diastolic blood pressure of adult and paediatric, but not neonatal patients together with a common stethoscope. The ERKA. Perfect-Aneroid Sphygmomanometer contains the following components:

- the manometer consisting of the main body, gauge, valve, bulb and spoon and
- the cuff consisting of cover, bladder and tubing.

The ERKA. Perfect-Aneroid comes in two model types: As Model ERKA. Perfect-Aneroid 48, with a 48mm scale diameter scale and as ERKA. Perfect-Aneroid 56, with a 56mm scale diameter. Both types differ solely in the size of the scale. The larger scale allows an easier reading, e.g. for users with reduced eyesight. The smaller 48mm device realizes a weight advantage while ensuring equal precision and functionality.
The ERKA. Perfect-Aneroid gauge works with a traditional gear driven pointer movement that is triggered by pressure induction on a sealed membrane. The

manometer features a brass chrome plated housing and a membrane protecting 2-tube technology. The mechanics function in exactly the same way in both diameter sizes. The device comes with a polyurethane coated wipeable cuff. The duo-tubing is made of latex-free silicone and the inflatable bladder in the cuff is made of polyurethane material. The cuffs meet the required biocompatibility standards and are substantially equivalent to the cuffs marketed under 510(k) clearance K071885 and K001333. The cuffs may be obtained in the following sizes:

- Pediatric: Limb circumference 14 cm - 21.5 cm
- Small adult: Limb circumference 20.5 cm – 28 cm
- Adult: Limb circumference 27 cm – 35 cm
- Large Adult: Limb circumference 34 cm – 43 cm
- Thigh: Limb circumference 42 cm – 54 cm

(5)
Intended Use statement:

The ERKA. Perfect-Aneroid sphygmomanometer is intended for the non-invasive blood pressure measurement of adult and paediatric, but not neonatal patients. The device is not designed, sold or intended for use except as indicated.

Restrictions:

The ERKA. Perfect-Aneroid sphygmomanometer is only to be used with ERKA. cuffs. Cuff size recommendations must be complied with in order to ensure blood pressure accuracy and safety.

(6)
Predicate Device Comparison Table

	ERKA. Perfect-Aneroid (48/56 mm scale diameter)	**Riester precisa N (63 mm scale diameter)**
General		
Scientific concept	non-invasive, non-automated blood pressure measurement by means of auscultation of the *Korotkoff and Riva Rocci* sounds	non-invasive, non-automated blood pressure measurement by means of auscultation of the *Korotkoff and Riva Rocci* sounds
Intended Use	non-invasive blood pressure measurement of adult and paediatric, but not neonatal patients	non-invasive blood pressure measurement of adult and paediatric patients
Pressure measurement	aneroid principle	aneroid principle
Pressure induction	manually by pump bulb	manually by pump bulb
Technical characteristics		

Design of Device	manometer including gauge and valve, cuff including inflatable bladder and tubing	manometer including gauge and valve, cuff including inflatable bladder and tubing
Pointer movement	gear driven	gear driven
Measurement range	0-300 mmHg	0-300 mmHg
Measurement accuracy	+/- 3 mmHg	+/- 3 mmHg
Dimensions	ERKA. dimensions as per datasheet. Dimensions of predicate device slightly different, however this does not have influence on performance	
Scale diameter	48mm or 56mm diameter, (technological solution remains exactly the same)	63mm
Scale graduation	2mmHg	2mmHg
Tubing	membrane protecting 2-tube concept	membrane protecting 2-tube concept
Tube material	silicone, latex-free	unknown
Valve	Precision air release valve	Precision air release valve
Cuff incl. bladder	PU coated wipeable, latex-free material	Various cotton and nylon cuffs
Cuff size	various	various
Material grades of housing and body	Partly different material grades used. Difference does not affect performance.	
Inflation method	manually by means of pump bulb	manually by means of pump bulb
Bulb material	latex-free, medical grade PVC	not known
Patient labeling		
Device identification	individual, traceable device number	individual, traceable device number
Instructions for Use[2]	as per Guidance on Medical Device Patient Labeling, IFU included in package	as per Guidance on Medical Device Patient Labeling, IFU included in package
Packaging container labeling	label on outer container identifies model, article no., manufacturer, serial no. and content	label on outer container identifies model, article no., manufacturer, serial no. and content
Device labeling	gauge clearly identifies measuring range, unit, device no.; manufacturer, model, symbol for IFU; cuff clearly identifies size, range, latex-free information, artery marking, manufacturer, cuff positioning	gauge clearly identifies measuring range, unit, device no.; manufacturer, model, symbol for IFU; cuff clearly identifies size, range, artery marking, manufacturer, cuff positioning
Indications for Use	The ERKA. Perfect-Aneroid sphygmomanometer is intended for the non-invasive blood pressure measurement of adult and paediatric, but not neonatal patients. The device is not designed, sold or intended for use except as indicated.	Precisa-N is a sphygmomanometer and is intended to measure the blood pressure (self-measurement)[3]

[2] The IFUs of the ERKA. devices and the predicate device may be found in Appendix B

[3] The RIESTER statement is shorter, however signifies fundamentally the same meaning. As required by European and FDA regulations ERKA. determined the Indications for Use in greater detail.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ERKA. Kallmeyer Medizintechnik GmbH & Co. KG
c/o Mr. Alexander Schapovalov
TUV SUD America, Inc.
1775 Old Highway 8
New Brighton, MN 55112-1891

JUN - 8 2011

Re: K103637
Trade/Device Names: ERKA. Perfect-Aneroid Sphygmomanometer and Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: May 18, 2011
Received: May 20, 2011

Dear Mr. Schapovalov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K103637

Section 4 - Indications for use statement

510(k) Number:	Unknown
Device Name:	ERKA. Perfect-Aneroid sphygmomanometer
Indications for Use:	The ERKA. Perfect-Aneroid sphygmomanometer is intended for the non-invasive blood pressure measurement of adult and paediatric, but not neonatal patients. The device is not designed, sold or intended for use except as indicated.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___yes___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K103637